MINIATURE RADIATION SOURCE WITH FLEXIBLE PROBE AND LASER DRIVEN THERMIONIC EMITTER

RELATED APPLICATIONS

The following application is a divisional application of U.S. patent application Ser. No. 09/311,792, filed May 13, 1999 now U.S. Pat. No. 6,195,411.

BACKGROUND OF THE INVENTION

The present invention relates to a highly miniaturized, low power, programmable radiation source for use in delivering predefined doses of radiation to a predefined region and more particularly to a miniaturized radiation source mounted in a flexible probe.

In the field of medicine, radiation is used for diagnostic, therapeutic and palliative treatment of patients. The conventional medical radiation sources used for these treatments include large fixed position machines as well as small, transportable radiation generating probes. The current state of the art treatment systems utilize computers to generate complex treatment plans.

These systems apply doses of radiation that are known to inhibit the growth of new tissue because the radiation affects dividing cells more than the mature cells found in nongrowing tissue. Thus, the tissue in the site of an excised tumor can be treated to prevent the regrowth of cancerous tissue and the recurrence of cancer. Alternatively, radiation can be applied to other areas of the body to inhibit tissue growth, for example the growth of new blood vessels inside the eye that can cause macular degeneration.

Conventional radiation treatments systems, such as the LINAC used for medical treatment, utilize a high power remote radiation source and direct a beam of radiation at a target area, such as tumor inside the body of a patient. This type of treatment is referred to as teletherapy because the radiation source is located a predefined distance, approximately one meter, from the target. This treatment suffers from the disadvantage that tissue disposed between the radiation source and the target is exposed to radiation.

An alternative treatment system utilizing a point source of radiation is disclosed in U.S. Pat. No. 5,153,900 issued to Nomikos et al., U.S. Pat. No. 5,369,679 to Sliski et al., and U.S. Pat. No. 5,422,926 to Smith et al., all owned by the assignee of the present application, all of which are hereby incorporated by reference. This system includes a miniaturized, insertable probe capable of producing low power radiation in predefined dose geometries disposed about a predetermined location. This type of treatment is referred to as brachytherapy because the source is located close to or in some cases within the area receiving treatment. One advantage of brachytherapy is that the radiation is applied primarily to treat a predefined tissue volume, without significantly affecting the tissue adjacent to the treated volume.

Typical radiation therapy treatment involves positioning the insertable probe into or adjacent to the tumor or the site where the tumor or a portion of the tumor was removed to treat the tissue adjacent the site with a "local boost" of radiation. In order to facilitate controlled treatment of the site, it is desirable to support the tissue portions to be treated at a predefined distances from the radiation source. Alternatively, where the treatment involves the treatment of surface tissue or the surface of an organ, it is desirable to control the shape of the surface as well as the shape of the radiation field applied to the surface.

The treatment can involve the application of radiation, either continuously or intermittently, over an extended period of time. Therefore, it is desirable that the insertable probe be adjustably supported in a compliant manner to accurately position the radiation source with respect to the treated site and accommodate normal minor movements of the patient, such as movements associated with breathing.

In many x-ray therapeutic procedures, x-ray probes of the type generally disclosed in U.S. Pat. No. 5,153,900 incorporate a relatively rigid tube enclosing an electron beam directed to an x-ray emitting target at its distal end. For example, in treatment of brain tumors, an x-ray probe having a rigid tube is used with a stereotactic frame affixed to the patient's skull, where the tube is advanced into a biopsy hole to the tumor location, as disclosed in U.S. Pat. No. 5,369,679. The rigidity of the tube is useful in ensuring that the x-ray emitting target is properly located. In other cases, it is desirable to have a flexible tube leading to the x-ray emitting target, for example, where it is desirable to pass the probe up the urethra to the bladder, for treatment of the bladder. Such a flexible probe is disclosed in U.S. Pat. No. 5,248,658.

However, it has been difficult to effectively treat tissue using the flexible probe of the latter patent.

Accordingly, it is an object of the present invention to provide an improved system for delivering radiation to a localized area.

It is a further object of the present invention to provide an improved highly miniaturized radiation source with a flexible probe.

SUMMARY OF THE INVENTION

The present invention is directed to a miniaturized radiation source at the end of a flexible probe or catheter. The flexible catheter extends along a probe axis between a proximal end and a distal end of the catheter. The radiation source, at the distal end of the catheter, includes a substantially rigid housing disposed about a substantially evacuated interior region extending along a beam axis from an electron source at an input end of the housing to a radiation transmissive window at an output end of the housing. The housing also includes a channel electron multiplier adapted for receiving electrons from the electron source and for producing free electrons at an output end of the channel electron multiplier and an electron accelerator adapted for establishing a potential difference in the interior region of the housing whereby the free electrons produced at the output end of the channel electron multiplier are accelerated toward a target at or near the window. The target produces x-radiation in response to incident accelerated free electrons.

Preferably, the electron accelerator includes a surface disposed about the beam axis between the electron source and the target on a ceramic and preferably monolithic, substrate. In one embodiment, the surface bears a semiconductor coating. The surface may be substantially conical in shape wherein the distance from the beam axis increases as a function of the distance from the electron source. The electron source can be a photocathode illuminated by laser energy, a field emitter or a thermionic emitter. The target and outer surface of the probe is preferably maintained at ground potential to reduce the risk of shock.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other objects of this invention, the various features thereof, as well as the invention itself, may be more fully understood from the following description, when read together with the accompanying drawings in which:

FIGS. 1A and 1B are a diagrammatic perspective view and a diagrammatic detail view, respectively, of a low power radiation source embodying the present invention;

FIGS. 2A and 2B are a perspective view and a sectional view, respectively, of an alternate form embodying the present invention;

FIG. 3 is a diagrammatic representation of a sheath adapted for use with the apparatus of FIG. 1;

FIG. 4 is a schematic block diagram of the embodiment of FIG. 1;

FIG. 5 is a diagrammatic view of a low power radiation treatment system having a flexible probe embodying the present invention; and

FIG. 6 is a diagrammatic view of a low power radiation source embodying the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is directed to a miniature, low power radiation producing probe which can be used for diagnostic, therapeutic and palliative treatment of patients. The radiation source in accordance with the present invention can made smaller than conventional radiation sources. In addition, the radiation source can be disposed at the distal end of the tip of a flexible (or rigid) tube or catheter which can be inserted into the body. In one embodiment, only a single high voltage wire is necessary for operation. The target and the outer surface of the probe are set at the ground potential to reduce the shock hazard of the device.

FIG. 1A shows an x-ray apparatus **10** embodying the present invention. Apparatus **10** includes a housing **12** and an elongated cylindrical probe **14** extending from housing **12** along a reference axis **16** to an x source assembly **19**. Preferably, the probe **14** is flexible, as described below, but in some cases may be rigid. The housing **12** encloses a high voltage power supply **12A**, a battery **12B** and a control system **12C**. The x-ray source assembly **19** has an electron source (cathode) **22** located in the distal end of the probe **14**. Electron source **22** is located in close proximity to a channel electron multiplier (CEM) **23** which receives electrons from the electron source **22**. An accelerator **24** is positioned between the CEM **23** and an x-ray emitting (in response to incident accelerated electrons) target **26**. The target underlies on x-ray transmissive window **27**. Probe **14** is integral with the housing **12** and extends toward the target **26**. In various embodiments, the x-ray emitting tip may be selectively shielded to control the spatial distribution of x-rays. In addition, the accelerator **24** may be magnetically shielded to prevent external magnetic fields from deflecting the beam away from designed impact points on the target.

FIG. 1B shows an x-ray source assembly **19'** for generating x-rays embodying the present invention. That source **19'** is adapted for placement at the end of a cylindrical element (flexible or rigid). In an alternate form, shown in FIG. 2A and 2B, an x-ray source **19"** is positioned within a compact housing **12**, the latter device is suitable to applying x-radiation body surface tissue.

In the various forms of x-ray source assembly **19**, the electron beam generator **22** may include a thermionic emitter (driven by a low voltage power source or laser) or a photocathode (irradiated by an LED or laser source) or a field emitter. A single high voltage power supply **12A** can be used to power the electron source (thermionic emitter) **22**, the CEM **23** and accelerator **24**. The accelerator **24** establishes an acceleration potential difference between the CEM **23** and the target **26** which is at ground potential. The beam generation and acceleration components can be adapted to establish a thin (e.g. 1 mm or less in diameter) electron beam within the assembly **19** along a nominally straight axis **16**.

Preferably, the CEM **23** is constructed as is well known and the electron multiplication value is predetermined as function of the intended use of the radiation source. Preferably, a high voltage of 1 Kvol is connected to input end of the CEM.

Preferably, the accelerator is constructed from a monolithic ceramic material and includes an interior channel formed in the shape of the surface of a cone, although other shapes may be used, for example parabolic. The accelerator is disposed between the CEM **23** and the target **26** along the axis of the electron beam trajectory whereby the distance of the surface from the beam increases as a function of the distance from the CEM23. Preferably, the surface includes a semiconductive coating **24A** which ensures that the voltage gradient in the accelerator is smooth and linear and helps to prevent breakdown which occurs when the electrons hit the walls of the accelerator.

In one form of the invention, the outer cylindrical portion of the x-ray source assembly **19** is a hollow evacuated cylinder made of a molybdenum-rhenium, (Mo—Re), molybdenum (Mo) or mu-metal body with an interior diameter of 2 mm, and an exterior diameter of 3 mm. Preferably, beryllium (Be) cap and having a distance from the electron source to the target is less than 2 mm. The target assembly **26** includes an emission element consisting of a small beryllium (Be) target element **26A** which is coated on the side exposed to the incident electron beam with a thin film or layer **26B** of a high-Z element, such as tungsten (W), uranium (U) or gold (Au). By way of example, with electrons accelerated to 30 keV-, a 2.2 micron thick tungsten film absorbs substantially all the incident electrons, while transmitting approximately 95% of any 30 keV-, 88% of any 20 keV-, and 83% of any 10 keV- x-rays generated in that layer. In the preferred embodiment, the beryllium target element **26A** is 0.5 mm thick with the result that 95% of the x-rays generated in directions normal to and toward the substrate **26A**, and having passed through the tungsten target, are then transmitted through the beryllium substrate and outward at the distal end of assembly **19**. While the target element **26A** shown in FIG. **3B** is in the form of a hemispherical layer, other shaped elements may be used, such as those having disk-like or conical shapes.

In some forms of the target, the window element **26A** may include a multiple layer film **26B**, where the differing layers may have different emission characteristics. By way of example, the first layer may have an emission (vs. energy) peak at a relatively low energy, and the second (underlying) layer may have an emission (vs. energy) peak at a relatively high energy. With this form of the invention, a low energy electron beam may be used to generate x-rays in the first layer (to achieve a first radiation characteristic) and high energy electrons may be used to penetrate through to the underlying layer (to achieve a second radiation characteristic). As an example, a 0.5 mm wide electron beam is emitted at the cathode and accelerated to 30 keV- through the anode, with 0.1 eV transverse electron energies, and arrives at the target assembly **26** downstream from the anode, with a beam diameter of less than 1 mm at the target assembly **26**. X-rays are generated in the target assembly **26** in accordance with preselected beam voltage, current, and target element **26B** composition. The x-rays thus generated pass through the beryllium target substrate **26A** with minimized loss in energy. As an alternative to beryllium, the

target substrate 26A may be made of carbon or other suitable material which permits x-rays to pass with a minimum loss of energy. An optimal material for target substrate 26A is carbon in its diamond form, since that material is an excellent heat conductor. Using these parameters, the resultant x-rays have sufficient energy to penetrate into soft tissues to a depth of a centimeter or more, the exact depth dependent upon the x-ray energy distribution.

The apparatus of FIGS. 2A and 2B is particularly adapted for full implantation into a patient, where the housing 12 a biocompatible outer surface and encloses both a high voltage power supply circuit 12A for establishing a drive voltage for the beam generator 22, and an associated battery 12B for driving that circuit 12A. In this case, an associated controller 12C establishes control of the output voltage of the high power supply circuit 12A, in the manner described below.

The apparatus of FIGS. 1A and 1B may be used in a manner where only the probe 14 and x-ray source assembly 19 are inserted into a patient while the housing 12 remains outside the patient, i.e., a transcutaneous form. In the latter form, some or all of the various elements shown within housing 12 may alternatively be remotely located.

In the transcutaneous form, the apparatus 10 may be used with an elongated closed end (or cup-shaped) sheath 34, as shown in FIG. 3, having a biocompatible outer surface, for example, fabricated of medical grade aliphatic polyurethane, as manufactured under the trademark Tecoflex by Thermedics, Inc., Woburn, Mass. With this configuration, the probe 14 is first inserted into the sheath 34. The sheath 34 and probe 14 are then inserted into the patient through the skin. Alternatively, a port may be inserted through the skin and attached to it, as for example a Dermaport port manufactured by Thermedics Inc., Woburn, Mass. The probe 14 is then inserted into the port.

The lining of the sheath or port can be configured as an x-ray shield by introducing barium sulfate or bismuth trioxide, or other x-ray shielding materials, into the sheath. If necessary, the probe 14 and housing 12 can be secured to the patient's body to prevent any relative motion during the extended time of treatment. An exemplary sheath 34 is shown in FIG. 3.

In one embodiment of the apparatus as shown in FIGS. 1A and 1B, the main body of the probe 14 can be made of a magnetically shielding material such as a mu-metal. Alternatively, the probe 14 can be made of a non-magnetic metal, preferably having relatively high values for Young's modulus and elastic limit. Examples of such material include molybdenum, rhenium or alloys of these materials. The outer cylindrical shell of the accelerator 24 can be made of the outer shell metal. The inner or outer surface of probe 14 can then be coated with a high permeability magnetic alloy such as permalloy (approximately 80% nickel and 20% iron), to provide magnetic shielding. Alternatively, a thin sleeve of mu-metal can be fitted over, or inside of that shell of accelerator 24. The x-ray apparatus 10 can then be used in environments in which there are dc and ac magnetic fields due to electrical power, the field of the earth, or other magnetized bodies nominally capable of deflecting the electron beam from the probe axis.

In implantable configurations, such as those of FIGS. 2A and 2B, the power supply 12A and target assembly 26 are preferably enclosed in a capsule to prevent current flow from the x-ray source to the patient. The closed housing 12 and probe 14 are, thus, encapsulated in a continuous outer shell of appropriate shielding material such as those mentioned previously.

The high voltage power supply 12A in each of the illustrated embodiments preferably satisfies three criteria: 1) small in size; 2) high efficiency to enable the use of battery power; and 3) independently variable x-ray tube voltage and current to enable the unit to be programmed for specific applications. A high-frequency, switch-mode power converter is used to meet these requirements. The most appropriate topology for generating low power and high voltage is a resonant voltage converter working in conjunction with a high voltage, Cockroft-Walton-type multiplier. Low-power dissipation, switch-mode power-supply controller-integrated circuits (IC) are currently available for controlling such topologies with few ancillary components.

The embodiment of FIGS. 2A and 2B can also be adapted for superficial usage, that is for direct placement on the skin of a patient. This form of the invention is particularly useful for x-ray treatment of skin lesions or tumors, or other dermatological applications. In FIGS. 2A and 2B, elements that correspond to elements in the embodiment of FIGS. 1A and 1B are denoted with the same reference designations. Apparatus 10' generates an electron beam in a channel 40 enclosed within housing 12, where that channel 40 corresponds to probe 14. In the present embodiment, of FIGS. 2A and 2B, the x-ray source assembly 19 functions in a manner similar to that described above. With the configuration of FIGS. 2A and 2B, low power x-rays may be directed to a desired skin region of a patient.

In all of the above-described embodiments, the x-ray emission element of the target assembly is adapted to be adjacent to or within the region to be irradiated. The proximity of the emission element to the targeted region, e.g. the tumor, eliminates the need for the high voltages of presently used machines, to achieve satisfactory x-ray penetration through the body wall to the tumor site. The low voltage also concentrates the radiation in the targeted tumor, and limits the damage to surrounding tissue and surface skin at the point of penetration. For example, the delivery of 4000 rads, as is required after a mastectomy, with a 40 kV, 20 uA electron beam, may require approximately 1 to 3 hours of radiation. However, since the x-ray source is, in this preferred embodiment, insertable proximate to, or into, the region-to-be-irradiated risk of incidental radiation exposure to other parts of the patient's body is significantly reduced.

Further, specificity in treating tumors may be achieved by tailoring the target and shield geometry and material at the emission site, for example as disclosed in U.S. Pat. No. PHLL-111, assigned to the assignee of the present invention,. This tailoring facilitates the control of energy and the spatial profile of the x-ray emission to ensure more homogenous distribution of the radiation throughout the targeted tumor.

FIG. 4 is a schematic representation of the x-ray source apparatus 10 shown in FIG. 1A. In that preferred configuration, the housing 12 is divided into a first portion 12' and a second portion 12". Enclosed within the first housing portion 12' is a rechargeable battery 12B, a recharge network 12D for the battery 12B, which is adapted for use with an external charger 50, and a telemetry network 12E, adapted to be responsive to an external telemetry device 52 to function in the manner described below. That portion 12' is coupled by cables to the second housing portion 12". The second housing portion 12" includes the high voltage power supply 12A, controller 12C and the probe 14, as well as the electron beam generating element 22. In one embodiment, the electron beam generator includes a thermionic emitter 22 driven by the power supply 12A. In operation, power supply 12A heats the thermionic emitter 22, which in turn generates